September 15, 2021

Vascular Solutions, Inc.
Julie Tapper
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K071727
Trade/Device Name: QXT Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Julie Tapper:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 28, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 10:20:34 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

Vascular Solution, Inc.
c/o Ms. Julie Tapper
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K071727
QXT™ Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: August 14, 2007
Received: August 15, 2007

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071727

Device Name: QXT™ Extraction Catheter

Indications for Use: The QXT catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vodney

ision Sign-Off)
ision of Cardiovascular Devices

510(k) Number K071727

510(k) Summary

As required by 21 CFR 807.92(c)

SEP 2 8 2007

510(k) Number: K071727

Date Prepared

June 22, 2007

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Julie Tapper Senior Regulatory Affairs Associate

Device Information

Trade Name: QXT™ Extraction Catheter
Common Name: Embolectomy catheter
Class: II
Classification Name: Embolectomy catheter
(21CFR 870.5150, Product Code DXE)

Predicate Device(s)

Pronto™ V3 Extraction Catheter (K052232 and K063371) manufactured by Vascular Solutions, Inc.

Diver™ C.E. Catheter (K051917 and K050276) submitted by ev3.

Export® XT Extraction Catheter (K040869 and K061059) manufactured by Medtronic Vascular, Inc.

Device Description

The QXT catheter is designed to aspirate or extract soft thrombus from arterial vasculature. It has a dual-lumen design—an extraction lumen that allows for the removal of thrombus by aspiration and a rapid-exchange guidewire lumen that accommodates ≤0.014″ diameter guidewires. A Y-adapter is bonded to the catheter's proximal end that facilitates the attachment of syringes and extension lines, and there is a self-sealing straight valve bonded to one port of the Y-adapter. The purpose of the straight valve is to provide a means of inserting and removing a stiffening mandrel, that is supplied with the device, while maintaining hemostasis during use. The catheter's outer diameter is a maximum of approximately 0.063″ and its working

length is approximately 137cm. The catheter is compatible with ≥6F guide catheters. There is a single radiopaque marker located near the distal tip, and the catheter's shaft has non-radiopaque positioning marks printed at approximately 95cm and 105cm proximal to the distal tip. Each device is supplied with a stiffening mandrel that is placed through the self-sealing straight valve, a 30mL VakLok syringe, and a 6 inch extension line that has a one-way stopcock. The QXT catheter is provided sterile and intended for single use.

Intended Use/Indications for Use

The QXT catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Summary of Testing

Bench testing was conducted on the QXT catheter and included an assessment of the device's physical properties and its ability to achieve its intended use. Bench tests were conducted as part of design verification activities and after aging the devices in simulated-aging conditions.

The results of the tests confirmed the suitability of the device for its intended use. Each bench test that was conducted is listed, below.

Visual inspection	Hub-to-proximal-shaft Bond Strength
Tortuosity	Extraction Lumen (mid-shaft) Thermal Bond Strength
Catheter Kink Resistance	Extraction Lumen to Distal Tip Bond Strength
Markerband visibility	Stiffening Wire Bond Strength
Thrombus extraction	Fluid Leak Under Pressure
Blood extraction	Guidewire Interface
Air Leak During Aspiration	Guide Catheter Interface

Packaging and product inspections were conducted after the devices were subjected to simulated-distribution conditions, as follows:

Pouch Visual Appearance	Product Visual Appearance
Product Containment	Labeling Legibility

Also, device biocompatibility testing was conducted, as follows:

Cytotoxicity, 929 MEM Elution	Prothrombin Time
Sensitization, Kligman Maximization	In Vitro Hemocompatibility
Intracutaneous Injection Test	Hemolysis
Systemic Toxicity	Lee & White Coagulation Assay
Material Mediated Pyrogen Test	

No QXT catheter clinical evaluations were conducted.

Statement of Equivalence

The QXT catheter is substantially equivalent to the currently marketed Pronto V3, Diver CE, and Export catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods.

Conclusions

The QXT catheter is substantially equivalent to the currently marketed Pronto V3, Diver CE, and Export catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.